April 3, 2025

Ossio Ltd.
% Dave McGurl
Vice President, Regulatory Affairs- Orthopedics
MCRA, LLC
803 7th Street NW, Third Floor
Washington, District of Columbia 20001

Re: K243760
Trade/Device Name: OSSIOfiber® Suture Anchor 2.5-3.5 mm
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: March 26, 2025
Received: March 26, 2025

Dear Dave McGurl:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243760

Device Name

OSSIOfiber® Suture Anchor 2.5-3.5 mm

Indications for Use *(Describe)*

The OSSIOfiber® Suture Anchors 2.5-3.5 mm, are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder, in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation. Specific indications are listed below:

• Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure
• Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers
• Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair (Tennis Elbow)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
OSSIOfiber® Suture Anchor 2.5-3.5 mm

Submitter:
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Date Prepared: Dec 06, 2024

Regulatory Contact:
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Name of Device: OSSIOfiber® Suture Anchor 2.5-3.5 mm

Common or Usual Name: Fastener, Fixation, Biodegradable, Soft Tissue

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II, 21 C.F.R. § 888.3030

Product Code: MAI

Primary Predicate:	Knotless SutureTak Anchors (K180594)
Additional Predicate:	OSSIOfiber® Suture Anchor (K213415)
Reference Devices:	OSSIOfiber® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail (K231272) OSSIOfiber® Threaded Trimmable Fixation Nail (K241277) OSSIOfiber® Compression Staple (K241932)

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to obtain clearance for the OSSIOfiber® Suture Anchor 2.5-3.5 mm.

Device Description

The OSSIOfiber® Suture Anchor 2.5-3.5 mm, consists of an anchor preloaded on an inserter. The anchor is made from poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. The polymer content degrades by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The fibers are made from minerals that are found in natural bone. As the OSSIOfiber® implants degrade, the load transfers to the surrounding anatomy throughout the healing period of the bone. Substantial degradation takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery. Sutures, needles and suture snare may also be provided with the device depending on configuration.

The OSSIOfiber® Suture Anchors 2.5-3.5mm are supplied sterile, for single patient use only.

The OSSIOfiber® Suture Anchors 2.5-3.5mm are designed to be used with commonly available orthopedic surgical tools such as ISO 9714 compatible instrumentations.

Indications For Use

The OSSIOfiber® Suture Anchors 2.5-3.5mm, are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder, in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation. Specific indications are listed below:

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- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure
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- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair (Tennis Elbow)

Summary of Technological Characteristics

The OSSIOfiber® Suture Anchors 2.5-3.5mm have the same intended use, and principles of operation, and similar indications for use, material composition and design characteristics as the predicate device Knotless SutureTak Anchors (K180594). The OSSIOfiber® Suture Anchors 2.5-3.5mm have identical intended use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as their additional predicate devices (K213415). Sutures with needles or suture snare are assembled with the anchor on an inserter and sterilized with EtO. The OSSIOfiber® subject devices are available in sizes appropriate for the children and adolescents patient population. Although there are slight design and material differences compared to the primary predicate, mechanical testing demonstrated at least equivalent performance both initially and after in-vitro degradation. Thus, any differences between the subject devices and their predicates do not raise different questions of safety and effectiveness.

Non-Clinical Data

Static pull-out and cyclic pull-out testing were performed to verify the strength and fixation properties of the OSSIOfiber® Suture Anchors 2.5-3.5mm, and to compare them to those of the primary predicate device (K180594). Testing was done initially and following in-vitro degradation. The in-vitro degradation profile was characterized.

Biocompatibility for the subject device was established primarily based on the referenced ISO 10993 data from previously cleared devices, as well as rationales. Biocompatibility for the OSSIOfiber® implants (Anchors) was established primarily based on the referenced ISO 10993 data from the previously cleared predicate (K213415) and reference devices (K231272, K241277, K241932) and a rationale. Biocompatibility for the

sutures and needles was established within their 510(k) clearances. Biocompatibility for the inserter was established based on a rationale.

Conclusions

The OSSIOfiber® Suture Anchor 2.5-3.5mm is as safe and effective as its primary predicate device, the Knotless SutureTak Anchor (K180594). The OSSIOfiber® Suture Anchors 2.5-3.5mm have the same intended use, and principles of operation, and similar indications for use, material composition and design characteristics as the primary predicate device. The OSSIOfiber® Suture Anchors 2.5-3.5mm have identical intended use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as their additional predicate devices (K213415). Any minor differences do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical testing data demonstrate that the OSSIOfiber® Suture Anchor 2.5-3.5mm is at least as safe and effective as the primary predicate device. Thus, the OSSIOfiber® Suture Anchors 2.5-3.5mm is substantially equivalent to its predicate devices.